510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k041975

B. Purpose for Submission:
New Device

C. Analyte:
Cholesterol (CHOL), HDL, LDL, Apolipoprotein A, and Apolipoprotein B

D. Type of Test:
Quality Control Materials

E. Applicant:
Maine Standards Co.

F. Proprietary and Established Names:
Validate Lipoprotein (LP) Calibration Verification Test Set

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1660 Quality Control Material (assayed and unassayed)

2. Classification:
   Class I

3. Product Code:
   JJY

4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:
   The VALIDATE Lipoprotein Calibration Verification Test Set is used by trained laboratory professionals for the quantitative determination of linearity, calibration verification of reportable range in manual, semi-automated and automated clinical chemistry systems for the following analytes: Cholesterol, HDL Cholesterol, LDL Cholesterol, Apolipoprotein A, and Apolipoprotein B

3. Special condition for use statement(s):
   For Prescription Use Only

4. Special instrument Requirements:
   N/A

I. Device Description:

Each VALIDATE Lipoprotein Calibration Verification Test Set contains Cholesterol, HDL Cholesterol, LDL Cholesterol, Apolipoprotein A, and Apolipoprotein B in a human serum protein base. Each test set consists of one bottle each of six (6) levels including zero. Each bottle of Levels 0 through 5 contains 5.0 milliliters.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   VALIDATE Chem 4 Calibration Verification Test Set

2. Predicate K number(s):
   k012120

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	For IN VITRO diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated semi-automated and manual chemistry systems.	For IN VITRO diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated semi-automated and manual chemistry systems.
Analytes	Cholesterol, HDL Cholesterol, LDL Cholesterol, Apolipoprotein A, and Apolipoprotein B	ALP, ALT, AMY, AST, CK, GGT, LD, LIP, TBIL, DBIL
Matrix	Human serum	protein
Number of Levels	6 including zero	6 including zero
Preparation	Liquid, ready to use	Liquid, ready to use
Packaging	5.0 mL each level	5.0 mL each level
Stability	Until Expiration	Until Expiration
Storage	-10 to 20^0 C	-10 to 20^0 C

K. Standard/Guidance Document Referenced (if applicable):
NCCLS EP6-P

L. Test Principle:
Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    Not Applicable

    b. *Linearity/assay reportable range:*
    Not Applicable

    c. *Traceability (controls, calibrators, or method):*
    No traceability provided.
    The VALIDATE Lipoprotein Calibration Verification Test set behaves in a manner suitable for the evaluation of calibration and the linear response of the listed analytes over the ranges tested when compared to the College of American Pathologists (CAP) General Chemistry Survey C/CN-3 B 2004.

    Equivalence testing was carried out on pre-production lots of VALIDATE Lipoprotein Calibration Verification Test Set using Roche Hitachi 911 with Roche reagents.

    Stability is assessed using a real time testing schedule. The labeling recommends that the product be stored at -10 to -20 C.

    d. *Detection limit:*
    N/A

    e. *Analytical specificity:*
    N/A

    f. *Assay cut-off:*
    N/A

2. Comparison studies:
    a. *Method comparison with predicate device:*
    N/A

    b. *Matrix comparison:*
    N/A

3. Clinical studies:
    a. *Clinical sensitivity:*
    N/A

b. Clinical specificity:
N/A

c. Other clinical supportive data (when a and b are not applicable):
N/A

4. Clinical cut-off:
N/A

5. Expected values/Reference range:
N/A

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.